A FLEXIBLE TIP

BACKGROUND

[0001] Catheters are tube-like medical devices that may be inserted into a body cavity, organ, or blood vessel for diagnostic or therapeutic reasons. Catheters may be designed for insertion into the vasculature and are available for a wide variety of purposes, including diagnosis, interventional therapy, drug delivery, drainage, perfusion, and the like. They may also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like. Catheters for each of these and other purposes can be introduced to numerous target sites within a patient's body by guiding the catheter through an incision made in the patient's skin.

[0002] Catheters generally have an elongated, flexible catheter body enclosing one or more lumens. The lumen(s) may extend from the proximal end to the distal end of the catheter body. The diameter of the lumen(s) may vary throughout the length of the catheter, such as when the lumens have a larger diameter at the proximal end than at the distal end, or the diameter of the lumen(s) may be uniform. When an inner body is placed substantially in the center of the outermost body, the lumens may be coaxially arranged. The catheter body may be relatively straight, inherently curved, or curved by insertion of a curved stiffening wire or wire guide through a catheter lumen. The catheter body may assume a straight or linear configuration, when free from external bending forces. The catheter body may be highly flexible and thus capable of passing through the tortuous twists and turns of a patient's vasculature. In some cases, the catheter body may have a shaped distal end portion including curves and bends, which are selected to facilitate introduction and placement of the catheter in the vascular system. A particular geometry of curves and/or

bends may be selected to accommodate the intended use of the catheter. The distal end of the catheter may also be equipped with an inflatable balloon to expand a medical device, such as a stent, and/or to dilate a vessel.

[0003] A lumen, extending through the length of a catheter, is often designed to enable the catheter to be employed in conjunction with a wire guide. This type of catheter is generally referred to as an over-the-wire catheter. There are many different types of over-the-wire catheters, including those adapted for dilation and stent delivery.

[0004] The wire guide is a small wire that is inserted into the patient in advance of an over-the-wire catheter. This wire may be inserted through a patient's skin and then fed along the desired conduit, such as a blood vessel, until it reaches the desired location. The smaller diameter and the malleability of the wire guide generally make it easier to feed through a potentially tortuous conduit, compared to the catheter itself. Once the wire guide has reached the location where treatment is to occur, the distal end of the over-the-wire catheter is fed over the proximal end of the wire guide. Next, the catheter may be advanced over the wire guide, and to the desired location, by applying force to the proximal end of the catheter.

[0005] The distal end of the catheter body may terminate in a catheter tip. There are a wide variety of different catheter tips, including rotating tips, shaped tips, cutting tips, and soft tips. Many of these distal catheter tips are designed to reduce the potential for trauma, such as the abrasion or puncture of the conduit, such as a blood vessel.

[0006] Reducing the potential for trauma to a conduit can involve modifying a variety of catheter tip design features. For example, some catheter tips are rounded and/or soft, which may reduce the risk of

abrasion by allowing the catheter to more easily move through the conduit. Other catheter tips are designed to be more flexible and/or compressible. A flexible tip may be more likely to deflect if forced against a wall of the conduit, rather than puncturing the conduit wall. Similarly a compressible tip may be less likely to puncture the wall of the conduit, since such a tip may reduce the force with which a catheter contacts an obstruction or the conduit wall. Additionally, a flexible and/or compressible catheter tip may allow the catheter to be more easily advanced over a wire guide. This is particularly important when the catheter is being advanced over a wire guide containing one or more sharp curves or turns. If the catheter can be easily advanced over a wire guide it may decrease the risk of abrasion and/or puncture.

BRIEF SUMMARY

[0007] In one aspect of the invention, there is an elongate flexible catheter tip comprising a longitudinal axis extending between a proximal end and a distal end. These aspects may further include a corrugated region located between the proximal end and the distal end.

[0008] In a further aspect of the invention, there is an elongate flexible tip comprising a proximal tip end, a distal tip end, and a corrugated region located between the proximal tip end and the distal tip end, wherein the proximal tip end is adjacently attached to an inner distal end of a dilation catheter. The dilation catheter comprises an elongate outer body comprising a longitudinal axis extending between an outer proximal end and an outer distal end. The dilation catheter further comprises an elongate inner body having a proximal region, located within the outer body and extending between the outer proximal end and the outer distal end, a distal region extending past the outer distal end and comprising the

inner distal end, and an inner lumen contained within the inner body. These aspects may further include an outer lumen defined by the outer body and the inner body, These aspects may also include a balloon comprising a proximal balloon leg attached to the outer distal end, a distal balloon leg attached to a distal end of the dilation catheter, and a balloon cavity defined by the proximal balloon leg and the distal balloon leg and in fluid communication with the outer lumen.

[0009] In a further aspect of the invention, there is an elongate flexible tip comprising a longitudinal axis extending between a proximal tip end and a distal tip end. In addition, a corrugated region is located between the proximal tip end and the distal tip end. These aspects may also include a tip lumen defined by the elongate flexible tip, such that the tip lumen is aligned with a wire guide lumen. Furthermore, the proximal tip end is adjacently attached to a distal body end of a dilation catheter. The dilation catheter comprises an elongate body with a longitudinal axis extending between a proximal body end and the distal body end, an inflation lumen and the wire guide lumen, wherein the inflation lumen and the wire guide lumen are parallel and are defined by the elongate body, and an intermediate region positioned between the proximal body end and the distal body end. These aspects may further include a balloon comprising a proximal balloon leg attached to the intermediate region, a distal balloon leg adjacently attached to the distal body end, and a balloon cavity defined by the proximal balloon leg and the distal balloon leg, and in fluid communication with the inflation lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The invention can be better understood with reference to the following drawings and description. The components in the figures are not

necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

[0011] **Fig. 1A** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip with a helical corrugation.

[0012] **Fig. 1B** illustrates, by means of a longitudinal three dimensional view, an example of an elongate flexible tip with a helical corrugation.

[0013] **Fig. 1C** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip with an accordion corrugation.

[0014] **Fig. 1D** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip with an accordion corrugation.

[0015] **Fig. 2** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip, wherein a distal end of the flexible tip includes a rounded end.

[0016] **Fig. 3** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end is adjacently attached to a distal balloon leg and an inner distal end.

[0017] **Fig. 4** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter, wherein the catheter includes an elongate flexible tip.

[0018] **Fig. 5** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein the flexible tip is attached to an inner distal end, forming a tip-end attachment.

[0019] **Fig. 6** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein an elongate inner body is reinforced with a braided coil.

[0020] **Fig. 7** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with a flexible tip, wherein the flexible tip is attached to a distal face.

[0021] **Fig. 8** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein an elongate inner body is composed of an inner material and an outer material.

[0022] **Fig. 9** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein the flexible tip is attached via an external mounting shoulder.

[0023] **Fig. 10** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end is adjacently attached to a distal balloon leg and a distal body end.

[0024] **Fig. 11** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter, wherein the catheter may include an elongate flexible tip.

[0025] **Fig. 12** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end is adjacently attached to a distal body end, forming a tip-end attachment.

[0026] **Fig. 13** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end may be adjacently attached to a distal body end via a distal face.

[0027] **Fig. 14** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end may be adjacently attached to a distal body end via an external mounting shoulder.

[0028] **Fig. 15** illustrates a cross-sectional view through lines A—A of **Figs. 3** to **9**.

[0029] **Fig. 16** illustrates a cross-sectional view through lines B—B of **Figs. 10** to **14**.

DETAILED DESCRIPTION

[0030] Reducing the potential for trauma to a conduit can involve modifying a variety of catheter tip design features. For example, some catheter tips are rounded and/or soft, while others are designed to be more flexible and/or compressible. A flexible tip may be more likely to deflect if forced against a wall of the conduit, while a compressible tip may be less likely to puncture the wall of the conduit. Additionally, a flexible and/or compressible catheter tip may allow the catheter to be more easily

advanced over a wire guide. This is particularly important when the catheter is being advanced over a wire guide containing one or more sharp curves or turns. If the catheter can be easily advanced over a wire guide it may further decrease the risk of abrasion and/or puncture. The following examples illustrate an elongate flexible catheter tip and the incorporation of this tip in a variety of catheters.

[0031] **Fig. 1A** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible tip **100** with a helical corrugation **101**. The helical corrugation **101** may comprise a spiral ridge **102** and a corresponding spiral groove **103** that are both continuous along the length of a corrugated region **160**.

[0032] The flexible tip **100** may have a longitudinal axis extending between a proximal end **110** and a distal end **120**. The flexible tip **100** may be made from any suitable material, including, but not limited to, polyethylene, polyamides, polyethers, polyether-block co-polyamide polymers, polyvinyl chloride (PVC), polystyrene, silicon co-polymer, polyolefin, polyurethane and combinations thereof. For example, the flexible tip **100** may be made from a polyether-block co-polyamide polymers, which may include a copolymer of amide monomers copolymerized with polyether monomers. Because the amide monomers may have greater structural "rigidity" in comparison to the polyether monomers, the rigidity of the resulting flexible tip **100** to deformation, such as bending or stretching, may be altered. The flexible tip **100** may also be made from laminates of these materials. One example of a suitable polyether-block co-polyamide polymer from which the flexible tip **100** can be made is PEBAX®, which is available from Elf Atofina, Philadelphia, PA. In one aspect, a blend of PEBAX® polyether-block co-polyamide polymers

may be used. In another configuration, the flexible tip **100** may be made from a polyamide polymer, such as nylon 12.

[0033] In one configuration, the flexible tip **100** may comprise a tube member **130**. The tube member **130** may define a lumen **150**, extending longitudinally from the proximal end **110** to the distal end **120** of the flexible tip **100**. In another configuration, the flexible tip **100** may be solid, such that no lumen is present (not shown). The flexible tip **100** and the corrugated region **160** may both vary in length. For example, the flexible tip **100** may range from about 2 mm to about 2 cm in length. In a preferred configuration, the flexible tip **100** may range from about 3 mm to about 1 cm in length.

[0034] The flexible tip **100** may include the corrugated region **160**, located between the proximal end **110** and the distal end **120**. The corrugated region **160** may be produced by applying a force to the precursor of tube member **130**. For example, the precursor to tube member **130** may be placed over a mandrel and the force may be applied in-line with the precursor of tube member **130**. The application of this type of force may cause the tube member **130** to buckle, producing the corrugated region **160**. In one configuration, the precursor of tube member **130** may be heated, using steam for example, during or after application of the force. Application of the heat during this process may provide the flexible tip **100** with memory, such that the flexible tip **100** may maintain the corrugated shape of the corrugated region **160** more efficiently.

[0035] The corrugated region **160** may possess several inherent features, including flexibility, deflectability, compressibility and conformability, which may contribute to the atraumatic nature of the flexible tip. For example, when a wire guide is not present, the corrugated region **160** may impart flexibility to the tip **100**. This flexibility may allow the tip

100 to preferentially deflect, if forced against an obstruction, such as a blood vessel wall, rather than puncturing the obstruction.

[0036] The corrugated region **160** may also contribute to the compressibility of the flexible tip **100**. When the flexible tip **100** contacts an obstruction, the compressibility of the flexible tip **100** may reduce the amount of force transferred to the obstruction by the flexible tip **100**. The corrugated region **160** of the flexible tip **100** may also provide a catheter tip which will better conform to the wire guide. This may be especially true if the catheter is being advanced over the wire guide containing sharp curves or bends. This conformability may result from the ability of the flexible tip to transfer torque around a sharp bend, when following the wire guide. The conformability, or the ability to transfer torque around a sharp bend, may allow a physician to more easily advance the corresponding catheter over the wire guide by reducing the amount of force that the physician must apply.

[0037] **Fig. 1B** illustrates, by means of a longitudinal three dimensional view, an example of an elongate flexible tip **100** with a helical corrugation **101**.

[0038] **Fig. 1C** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip **100** with an accordion corrugation **121**. In this configuration, the corrugated region **160** may be defined by an adjacent proximal tube portion **107** and an adjacent distal tube portion **108** and may further comprise a plurality of ridges **112** that may be interspersed with a plurality of grooves **113**. The elongate flexible catheter tip may also include ridges alone or grooves alone. The ridges **112** may have an outer diameter **114** that is greater than the outer diameter of the tube member **130** and/or the adjacent tube portions **107** and **108**. The grooves may have an inner diameter **115** that is smaller

than the inner diameter of the tube member **130** and/or the adjacent tube portions **107** and **108**.

[0039] The tube member **130** and the corrugated region **160** may also comprise a tube wall **131** that is defined by an inner lumen surface **132** and an outer tube surface **133**. In this configuration, the tube wall **131** may have a substantially uniform thickness throughout the length of the tube member **130**. That is, the thickness of the tube wall **131** may be substantially the same, whether the thickness is measured along the adjacent portions **107**, **108** or at the ridges **114** or grooves **113** of the corrugated region **160**.

[0040] **Fig. 1D** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip **100** with an accordion corrugation **121**. In this configuration, the grooves **113** may have an inner diameter **116** that is substantially the same as the inner diameter of the tube member **130** and/or the adjacent tube portions **107** and **108**.

[0041] **Fig. 2** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible tip **200**, wherein a distal end **205** of the flexible tip **200** includes a rounded end **210**. The flexible tip **200** may have a longitudinal axis extending between a proximal end **215** and the distal end **205**. The flexible tip **200** may include a corrugated region **220**, which may be located between the proximal end **215** and the distal end **205**.

[0042] The rounded end **210** may enhance the deflectability of the flexible tip **200**. In one configuration, the rounded end **210** may be integral with or formed from the flexible tip **200**. In another configuration, the rounded end **210** may be a separate piece or component that is attached to the distal end of the flexible tip **200**. Thus, the rounded end **210** may be

made of a material which is of a lower durometer than the flexible tip **200**, thus providing enhanced softness for the rounded end **210**. In another embodiment, the rounded end **210** may be a separate piece of component that possesses an inner diameter that is smaller than an inner diameter of the flexible tip **200**. The enhanced softness of the rounded end **210** may help to prevent abrasions or snagging on obstructions, as the flexible tip **200** is advanced through a conduit. In addition, it may further improve the deflectability of the flexible tip **200**.

[0043] A catheter having a flexible tip containing a corrugated region may be employed for a variety of applications, including diagnosis, interventional therapy, drug delivery, drainage, perfusion, and the like. Such a catheter may also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like. Furthermore a flexible tip containing a corrugated region may be incorporated into a dilation catheter, wherein a balloon may be attached to the catheter (and/or tip) using a variety of attachment configurations.

[0044] For example, **Fig. 3** illustrates, by means of a longitudinal cross-sectional view, an example of anelongate dilation catheter **300** with an elongate flexible tip **302**, wherein a proximal tip end **303** is adjacently attached to a distal balloon leg **305** and an inner distal end **310**. The dilation catheter **300** may be composed of an elongate outer body **315** and an elongate inner body **320**. The outer body **315** may have a longitudinal axis extending between an outer proximal end **317** and an outer distal end **318**. The outer body **315** and the inner body **320** may define an outer lumen **325** therebetween. The inner body **320** may include a proximal region **327**, located within the outer body **315** and extending between the outer proximal end **317** and the outer distal end **318**. Furthermore, the inner body **320** may have a distal region **328**, extending past the outer distal end

318 and comprising the inner distal end **310**. The inner body **320** may contain a single inner lumen **330**.

[0045] The elongate flexible tip **302** may include the proximal tip end **303**, a distal tip end **335**, and a corrugated region **340** located between the proximal tip end **303** and the distal tip end **335**. The distal tip end **335** may be integral with a rounded distal end **345** or the rounded distal end **345** may be a separate piece or component that is attached to the distal tip end **335**.

[0046] The dilation catheter **300** may be fitted with a balloon **350**. The balloon **350** may have a balloon cavity **355** in fluid communication with the outer lumen **325**, wherein the balloon cavity **355** may be defined by a proximal balloon leg **360** and the distal balloon leg **305**. The proximal balloon leg **360** may be attached to the outer distal end **318**. The proximal tip end **303**, the distal balloon leg **305**, and the inner distal end **310** may be adjacently attached. In one configuration, the proximal tip end **303** may be sandwiched between the distal balloon leg **305** and the inner distal end **310**.

[0047] In a further example, **Fig. 4** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **400**, wherein the catheter **400** may include an elongate flexible tip **405**. The dilation catheter **400** may have an elongate outer body **410** and an elongate inner body **415**. The outer body **410** may have a longitudinal axis extending between an outer proximal end **420** and an outer distal end **425**. The outer body **410** and the inner body **415** may define an outer lumen **430** therebetween. The inner body **415** may include a proximal region **435**, located within the outer body **410** and extending between the outer proximal end **420** and the outer distal end **425**. Furthermore, the inner body **415** may have a distal region **440**, extending past the outer distal end

425 and comprising an inner distal end **445**. The inner body **415** may contain a single inner lumen **450**.

[0048] The elongate flexible tip **405** may include a proximal tip end **455**, a distal tip end **460**, and a corrugated region **465** located between the proximal tip end **455** and the distal tip end **460**. In one configuration, the inner distal end **445** may be attached to the proximal tip end **455**, forming a tip-end attachment **470**. Furthermore, the distal tip end **460** may be integral with a rounded distal end **475**. In another configuration, the rounded distal end **475** may be a separate piece or component that is attached to the distal tip end **460**.

[0049] The dilation catheter **400** may be fitted with a balloon **480**, having a proximal balloon leg **482** and a distal balloon leg **483**. The proximal balloon leg **482** may be attached to the outer distal end **425**. The distal balloon leg **483** may be attached adjacent to the tip-end attachment **470**. It is worth noting that an "adjacent attachment", as used throughout this document, includes an operable connection or a functional connection, such that there may be intervening layers between the two pieces, components or members that are being attached. Furthermore, "adjacently attached" and "attached adjacent to", have the same meaning as that defined for an adjacent attachment. The balloon **480** may have a balloon cavity **485** in fluid communication with the outer lumen **430**, wherein the balloon cavity **485** is defined by the distal balloon leg **482** and the proximal balloon leg **483**.

[0050] In another example, **Fig. 5** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **500** with an elongate flexible tip **505**, wherein the tip **505** is attached to an inner distal end **510**, forming a tip-end attachment **515**. The dilation catheter **500** may be composed of an elongate outer body **520** and an elongate

inner body **525**. The outer body **520** may have a longitudinal axis extending between an outer proximal end **527** and an outer distal end **528**. The outer body **520** and the inner body **525** may define an outer lumen **530** therebetween. The inner body **525** may include a proximal region **535**, located within the outer body **520** and extending between the outer proximal end **527** and the outer distal end **528**. Furthermore, the inner body **525** may have a distal region **540**, extending past the outer distal end **528** and comprising the inner distal end **510**. The inner body **525** may contain a single inner lumen **545**.

[0051] The elongate flexible tip **505** may include a proximal tip end **547**, a distal tip end **548**, and a corrugated region **550** located between the proximal tip end **547** and the distal tip end **548**. In one configuration, the inner distal end **510** may be attached adjacent to the proximal tip end **547**, forming the tip-end attachment **515**. Furthermore, the distal tip end **548** may be integral with a rounded distal end **555**. In another configuration, the rounded distal end **555** may be a separate piece or component that is attached to the distal tip end **548**.

[0052] The dilation catheter **500** also may be fitted with a balloon **560**, having a proximal balloon leg **562** and a distal balloon leg **563**. The proximal balloon leg **562** may be attached to the outer distal end **528**, while the distal balloon leg **563** may be attached to the distal region **540**. The balloon **560** may have a balloon cavity **565** in fluid communication with the outer lumen **530**, wherein the balloon cavity **565** may be defined by the distal balloon leg **563** and the proximal balloon leg **562**.

[0053] In an additional example, **Fig. 6** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **600** with an elongate flexible tip **602**, wherein an elongate inner body **605** is reinforced with a braided coil **607**. The dilation catheter **600**

may be composed of an elongate outer body **610** and the elongate inner body **605**. The outer body **610** may have a longitudinal axis extending between an outer proximal end **612** and an outer distal end **613**. The outer body **610** and the inner body **605** may define an outer lumen **615** therebetween. The inner body **605** may include a proximal region **620**, located within the outer body **610** and extending between the outer proximal end **612** and the outer distal end **613**. Furthermore, the inner body **605** may have a distal region **625**, extending past the outer distal end **613** and comprising an inner distal end **630**. The inner body **605** may contain a single inner lumen **635**.

[0054] The braided coil **607** may serve to reinforce the inner body **605**. The braided coil **607** may be imbedded in the inner body **605**. In another configuration, the braided coil **607** may be adhered to the exterior or the interior of the inner body **605**. The braided coil **607** may extend throughout the entirety of the inner body **605** or the braided coil **607** may only extend through a portion of the inner body **605**. The tightness of the braided coil **607** may affect its flexibility and thus the flexibility of the inner body **605**. If the tightness of the braided coil **607** is decreased, the flexibility of the braided coil **607**, and the corresponding inner body **625**, may be increased. The tightness of the braided coil **607** may be uniform throughout its length or it may vary throughout its length. The flexibility of the inner body **605** may vary throughout the length of the inner body **605**. This may be accomplished by gradually decreasing the tightness of the braided coil **607** throughout the length of the inner body **605**. In one configuration, the braided coil **607** may be constructed from a variety of materials. For example, materials may include stainless steel and nitinol.

[0055] The elongate flexible tip **602** may include a proximal tip end **640**, a distal tip end **645**, and a corrugated region **650** located between the proximal tip end **640** and the distal tip end **645**. In one configuration, the

proximal tip end **640** may be attached adjacent to the inner distal end **630** (not shown). In another configuration, the proximal tip end **640** may be integral with the inner distal end **630**. Furthermore, the distal tip end **645** may be integral with a rounded distal end **651** or the rounded distal end **651** may be a separate piece or component that is attached to the distal tip end **645**.

[0056] The dilation catheter **600** may be fitted with a balloon **655**, having a proximal balloon leg **660** and a distal balloon leg **661**. The proximal balloon leg **660** may be attached to the outer distal end **613**. The distal balloon leg **661** may be attached to inner distal end **630**. The balloon **655** may have a balloon cavity **665** in fluid communication with the outer lumen **615**, wherein the balloon cavity **665** is defined by the proximal balloon leg **660** and the distal balloon leg **661**.

[0057] In another example, **Fig. 7** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **700** with a flexible tip **705**, wherein the tip may be attached to a distal face **707**. The dilation catheter **700** may be composed of an elongate outer body **710** and an elongate inner body **715**. The outer body **710** may have a longitudinal axis extending between an outer proximal end **716** and an outer distal end **717**. The outer body **710** and the inner body **715** may define an outer lumen **720** therebetween. The inner body **715** may include a proximal region **725**, located within the outer body **710** and extending between the outer proximal end **716** and the outer distal end **717**. Furthermore, the inner body **715** may have a distal region **730**, extending past the outer distal end **717** and comprising an inner distal end **735**. The inner body **715** may contain a single inner lumen **740**.

[0058] The dilation catheter **700** also may be fitted with a balloon **745** having a proximal balloon leg **750** and a distal balloon leg **755**. The

proximal balloon leg **750** may be attached to the outer distal end **717**. The distal balloon leg **755** may be attached to the inner distal end **735**, forming a distal bonding region **760**. The distal bonding region **760** may form the distal face **707**. In one configuration, the distal face **707** may form an angular groove, circumscribing the inner lumen **740**. In another configuration, the distal face **707** may be a flat surface, perpendicular to the longitudinal axis of the dilation catheter **700** (not shown). The balloon **745** may have a balloon cavity **770** in fluid communication with the outer lumen **720**, wherein the balloon cavity **770** is defined by the distal balloon leg **755** and the proximal balloon leg **750**.

[0059] The elongate flexible tip **705** may include a proximal tip end **772**, a distal tip end **773**, and a corrugated region **775** located between the proximal tip end **772** and the distal tip end **773**. In one configuration, the proximal tip end **772** may be attached adjacent to distal face **707**. Furthermore, the distal tip end **773** may be integral with a rounded distal end **780** or the rounded distal end **780** may be a separate piece or component that is attached to the distal tip end **773**.

[0060] In an additional example, **Fig. 8** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **800** with an elongate flexible tip **802**, wherein an elongate inner body **805** is composed of an inner material **806** and an outer material **807**. The dilation catheter **800** may be composed of an elongate outer body **810** and the elongate inner body **805**. The outer body **810** may have a longitudinal axis extending between an outer proximal end **812** and an outer distal end **813**. The outer body **810** and the inner body **805** may define an outer lumen **815** therebetween. The inner body **805** may include a proximal region **820**, located within the outer body **810** and extending between the outer proximal end **812** and the outer distal end **813**. Furthermore, the inner body **805** may have a distal region **825**, extending

past the outer distal end **813** and comprising an inner distal end **830**. In addition, the outer material **807** may be of a lower durometer than the inner material **806**. The inner body **805** may define a single inner lumen **835**.

[0061] The elongate flexible tip **802** may include a proximal tip end **840**, a distal tip end **845**, and a corrugated region **850** located between the proximal tip end **840** and the distal tip end **845**. The flexible tip **802** may be formed from the outer material **807** of the inner body **805**. In one configuration, the distal tip end **845** may be integral with a rounded distal end **855** or the rounded distal end **855** may be a separate piece or component that is attached to the distal tip end **845**.

[0062] The dilation catheter **800** may be fitted with a balloon **860**, having a proximal balloon leg **862** and a distal balloon leg **863**. The proximal balloon leg **862** may be attached to the outer distal end **813**. The distal balloon leg **863** may be attached to the inner distal end **830**. In another configuration, the distal balloon leg **863** may be attached to the flexible tip **802** (not shown). The balloon **860** may have a balloon cavity **865** in fluid communication with the outer lumen **815**, wherein the balloon cavity **865** is defined by the proximal balloon leg **862** and the distal balloon leg **863**.

[0063] In another example, **Fig. 9** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **900** with an elongate flexible tip **905**, wherein the flexible tip **905** may be attached via an external mounting shoulder **907**. The dilation catheter **900** may be composed of an elongate outer body **910** and an elongate inner body **915**. The outer body **910** may have a longitudinal axis extending between an outer proximal end **917** and an outer distal end **918**. The outer body **910** and the inner body **915** may define an outer lumen **920** therebetween. The inner body **915** may include a proximal region **922**, located within the outer

body **910** and extending between the outer proximal end **917** and the outer distal end **918**. Furthermore, the inner body **915** may have a distal region **923**, extending past the outer distal end **918** and comprising an inner distal end **925**. The inner body **915** may contain a single inner lumen **930**.

[0064] The dilation catheter **900** may be fitted with a balloon **935**, having a proximal balloon leg **937** and a distal balloon leg **938**. The proximal balloon leg **937** may be attached to the outer distal end **918**. The distal balloon leg **938** may be attached to the distal region **923**, forming the external mounting shoulder **907**. The balloon **935** may have a balloon cavity **940** in fluid communication with the outer lumen **920**, wherein the balloon cavity **940** is defined by the proximal balloon leg **937** and the distal balloon leg **938**.

[0065] The elongate flexible tip **905** may include a proximal tip end **945**, a distal tip end **950**, and a corrugated region **955** located between the proximal tip end **945** and the distal tip end **950**. The proximal tip end **945** may be attached to the external mounting shoulder **907**. Furthermore, the distal tip end **950** may be integral with a rounded distal end **956** or the rounded distal end **955** may be a separate piece or component that is attached to the distal tip end **950**.

[0066] In a further example, **Fig. 10** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **1000** with an elongate flexible tip **1002**, wherein a proximal tip end **1003** is adjacently attached to a distal balloon leg **1005** and a distal body end **1010**. The dilation catheter **1000** may be composed of an elongate body **1015**. The elongate body **1015** may have a longitudinal axis extending between a proximal body end **1017** and a distal body end **1010**. In addition, the elongate body **1015** may define parallel dual lumens, an inflation lumen **1025** and a wire guide lumen **1030**, wherein the lumens

1025 and **1030** extend longitudinally through the elongate body **1015**. The wire guide lumen **1030** extends through the distal body end **1010**, whereas the inflation lumen **1025** extends to an intermediate region **1018**. The intermediate region **1018** may be positioned between the proximal body end **1017** and the distal body end **1010**.

[0067] The elongate flexible tip **1002** may comprise a longitudinal axis extending between the proximal tip end **1003** and a distal tip end **1035**. A corrugated region **1040** may be located between the proximal tip end **1003** and the distal tip end **1035**. The distal tip end **1035** may be integral with a rounded distal end **1045** or the rounded distal end **1045** may be a separate piece or component that is attached to the distal tip end **1035**. Additionally, the elongate flexible tip **1002** may comprise a tip lumen **1050** extending from the proximal tip end **1003** through the rounded distal end **1045**, wherein the tip lumen **1050** is aligned with the wire guide lumen **1030**.

[0068] The dilation catheter **1000** may be fitted with a balloon **1055**. The balloon **1055** may have a balloon cavity **1057** in fluid communication with the inflation lumen **1025**, wherein the balloon cavity **1057** may be defined by a proximal balloon leg **1060** and the distal balloon leg **1005**. The proximal balloon leg **1060** may be attached to the intermediate region **1018**. The distal balloon leg **1005** may be adjacently attached to the distal body end **1010** and the proximal tip end **1003**. In one configuration, the proximal tip end **1003** may be sandwiched between the distal balloon leg **1005** and the distal body end **1010**.

[0069] In a further example, **Fig. 11** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **1100**, wherein the catheter **1100** may include an elongate flexible tip **1105**. The dilation catheter **1100** may be composed of an elongate body **1120**. The elongate body **1120** may have a longitudinal axis

extending between a proximal body end **1122**, and a distal body end **1125**. In addition, the elongate body **1120** may define parallel dual lumens, a wire guide lumen **1130** and an inflation lumen **1135**, wherein the lumens **1130** and **1135** extend longitudinally through the elongate body **1120**. The wire guide lumen **1130** extends through the distal body end **1125**, whereas the inflation lumen **1135** extends to an intermediate region **1123**. The intermediate region **1123** may be positioned between the proximal body end **1122** and the distal body end **1125**.

[0070] The elongate flexible tip **1105** may comprise a longitudinal axis extending between a proximal tip end **1155** and a distal tip end **1160**. A corrugated region **1165** may be located between the proximal tip end **1155** and the distal tip end **1160**. In one configuration, the proximal tip end **1155** is adjacently attached to the distal body end **1125**, forming a tip-end attachment **1170**. The distal tip end **1160** may be integral with a rounded distal end **1175** or may be a separate piece or component that is attached to the distal tip end **1160**. Additionally, the elongate flexible tip **1105** may comprise a tip lumen **1180** extending from the proximal tip end **1155** through the rounded distal end **1175**, wherein the tip lumen **1180** is aligned with the wire guide lumen **1130**.

[0071] The dilation catheter **1100** may be fitted with a balloon **1180**, having a proximal balloon leg **1182** and a distal balloon leg **1183**. The proximal balloon leg **1182** may be attached to the intermediate region **1123**. The distal balloon leg **1183** may be adjacently attached to the distal body end **1125**, the proximal tip end **1155**, and the tip-end attachment **1170**. The balloon **1180** may have a balloon cavity **1185** in fluid communication with the inflation lumen **1135**, wherein the balloon cavity **1185** is defined by the distal balloon leg **1182** and the proximal balloon leg **1183**.

[0072] In another example, **Fig. 12** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **1200** with an elongate flexible tip **1205**, wherein a proximal tip end **1247** is adjacently attached to a distal body end **1210**, forming a tip-end attachment **1215**. The dilation catheter **1200** may be composed of an elongate body **1220**. The elongate body **1220** may have a longitudinal axis extending between a proximal body end **1225**, and the distal body end **1210**. In addition, the elongate body **1210** may define parallel dual lumens, a wire guide lumen **1230** and an inflation lumen **1235**, wherein the lumens **1230** and **1235** extend longitudinally through the elongate body **1220**. The wire guide lumen **1230** extends through the distal body end **1210**, whereas the inflation lumen **1235** extends to an intermediate region **1227**. The intermediate region **1227** may be positioned between the proximal body end **1225** and the distal body end **1210**.

[0073] The elongate flexible tip **1205** may comprise a longitudinal axis extending between the proximal tip end **1247** and a distal tip end **1248**. A corrugated region **1250** may be located between the proximal tip end **1247** and the distal tip end **1248**. The distal body end **1210** may be adjacently attached to the proximal tip end **1247**, forming the tip-end attachment **1215**. In one configuration, the distal tip end **1248** may be integral with a rounded distal end **1255** or the rounded distal end **1255** may be a separate piece or component that is attached to the distal tip end **1248**. Additionally, the elongate flexible tip **1205** may comprise a tip lumen **1260** extending from the proximal tip end **1247** through the rounded distal end **1255**, wherein the tip lumen **1260** is aligned with the wire guide lumen **1230**.

[0074] The dilation catheter **1200** also may be fitted with a balloon **1265**, having a proximal balloon leg **1267** and a distal balloon leg **1268**. The proximal balloon leg **1267** may be attached to the intermediate region

1227, while the distal balloon leg **1268** may be adjacently attached to the distal body end **1210**. The balloon **1265** may have a balloon cavity **1270** in fluid communication with the inflation lumen **1235**, wherein the balloon cavity **1270** may be defined by the distal balloon leg **1268** and the proximal balloon leg **1267**.

[0075] In another example, **Fig. 13** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **1300** with an elongate flexible tip **1305**, wherein a proximal tip end **1372** may be adjacently attached to a distal body end **1325** via a distal face **1307**. The dilation catheter **1300** may be composed of an elongate body **1320**. The elongate body **1320** may have a longitudinal axis extending between a proximal body end **1322**, and the distal body end **1325**. In addition, the elongate body **1320** may define parallel dual lumens, a wire guide lumen **1330** and an inflation lumen **1335**, wherein the lumens **1330** and **1335** extend longitudinally through the elongate body **1320**. The wire guide lumen **1330** extends through the distal body end **1325**, whereas the inflation lumen **1335** extends to an intermediate region **1323**. The intermediate region **1323** may be positioned between the proximal body end **1322** and the distal body end **1325**.

[0076] The dilation catheter **1300** also may be fitted with a balloon **1345** having a proximal balloon leg **1350** and a distal balloon leg **1355**. The proximal balloon leg **1350** may be attached to the intermediate region **1323**. The distal balloon leg **1355** may be adjacently attached to the distal body end **1325**, forming a distal bonding region **1360**, wherein the distal bonding region **1360** may form the distal face **1307**. In one configuration, the distal face **1307** may comprise an angular groove, circumscribing the wire guide lumen **1330**. In another configuration, the distal face **1307** comprises a flat surface, circumscribing the wire guide lumen **1330** (not shown). The balloon **1345** may have a balloon cavity **1370** in fluid

communication with the inflation lumen **1335**, wherein the balloon cavity **1370** is defined by the distal balloon leg **1355** and the proximal balloon leg **1350**.

[0077] The elongate flexible tip **1305** may comprise a longitudinal axis extending between the proximal tip end **1372** and a distal tip end **1373**. A corrugated region **1375** may be located between the proximal tip end **1372** and the distal tip end **1373**. The distal tip end **1373** may be integral with a rounded distal end **1380** or the rounded distal end **1380** may be a separate piece or component that is attached to the distal tip end **1373**. The proximal tip end **1372** may be adjacently attached to the distal body end **1325** via the distal face **1307**. Additionally, the elongate flexible tip **1305** may comprise a tip lumen **1377** extending from the proximal tip end **1372** through the rounded distal end **1380**, wherein the tip lumen **1377** is aligned with the wire guide lumen **1330**.

[0078] In another example, **Fig. 14** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter **1400** with an elongate flexible tip **1405**, wherein a proximal tip end **1445** may be adjacently attached to a distal body end **1415** via an external mounting shoulder **1407**. The dilation catheter **1400** may be composed of an elongate body **1410**. The elongate body **1410** may have a longitudinal axis extending between a proximal body end **1412**, and the distal body end **1415**. In addition, the elongate body **1410** may define parallel dual lumens, an inflation lumen **1420** and a wire guide lumen **1425**, wherein the lumens **1420** and **1425** extend longitudinally through the elongate body **1410**. The wire guide lumen **1425** extends through the distal body end **1415**, whereas the inflation lumen **1420** extends to an intermediate region **1413**. The intermediate region **1413** may be positioned between the proximal body end **1412** and the distal body end **1415**.

[0079] The dilation catheter **1400** may be fitted with a balloon **1435**, having a proximal balloon leg **1437** and a distal balloon leg **1438**. The proximal balloon leg **1437** may be attached to the intermediate region **1413**. The distal balloon leg **1438** may be adjacently attached to the distal body end **1415**, forming the external mounting shoulder **1407**. The balloon **1435** may have a balloon cavity **1440** in fluid communication with the inflation lumen **1420**, wherein the balloon cavity **1440** is defined by the proximal balloon leg **1437** and the distal balloon leg **1438**.

[0080] The elongate flexible tip **1405** may comprise a longitudinal axis extending between the proximal tip end **1445** and a distal tip end **1450**. A corrugated region **1455** may be located between the proximal tip end **1445** and the distal tip end **1450**. The proximal tip end **1445** may be adjacently attached to the distal body end **1415** and the distal balloon leg via the external mounting shoulder **1407**. Furthermore, the distal tip end **1450** may be integral with a rounded distal end **1456** or the rounded distal end **1456** may be a separate piece or component that is attached to the distal tip end **1450**. Additionally, the elongate flexible tip **1405** may comprise a tip lumen **1457** extending from the proximal tip end **1445** through the rounded distal end **1456**, wherein the tip lumen **1457** is aligned with the wire guide lumen **1425**.

[0081] **Fig. 15** illustrates a cross-sectional view through lines A—A of **Figures 3** thru **9**. The dilation catheters of **Figures 3** thru **9** may comprise an elongate outer body **1505** and an elongate inner body **1510**. The outer body **1505** and the inner body **1510** may define an outer lumen **1515** therebetween. The inner body **1510** may contain a single inner lumen **1520**.

[0082] **Fig. 16** illustrates a cross-sectional view through lines B—B of **Figures 10** thru **14**. The dilation catheters of **Figures 10** thru **14** may

comprise an elongate outer body **1605**, wherein the elongate body **1605** may contain parallel dual lumens, an inflation lumen **1610** and a wire guide lumen **1615**.

[0083] It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention.